



**World Health
Organization**

Patient Safety

A World Alliance for Safer Health Care

Introduction to Patient Safety Research

Presentation 11: Identifying Solutions: Cluster Randomized Clinical Trial



2: Introduction: Study Details

■ Full Reference

- **MERIT study investigators. Introduction of the medical emergency team (MET) system: a cluster-randomised controlled trial. The Lancet 2005, 365:2091-2097**

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Introduction of the medical emergency team (MET) system: a cluster-randomised controlled trial

MERIT study investigators¹

Summary

Background

Patients with cardiac arrests or who die in general wards have often received delayed or inadequate care. We investigated whether the medical emergency team (MET) system could reduce the incidence of cardiac arrests, unplanned admissions to intensive care units (ICU), and deaths.

Methods

We randomised 23 hospitals in Australia to continue functioning as usual (n=11) or to introduce a MET system (n=12). The primary outcome was the composite of cardiac arrest, unexpected death, or unplanned ICU admission during the 6-month study period after MET activation. Analysis was by intention to treat.

Findings

Introduction of the MET increased the overall calling incidence for an emergency team (3.1 vs 8.7 per 1000 admissions, $p=0.0001$). The MET was called to 30% of patients who fulfilled the calling criteria and who were subsequently admitted to the ICU. During the study, we recorded similar incidence of the composite primary outcome in the control and MET hospitals (5.86 vs 5.31 per 1000 admissions, $p=0.640$), as well as of the individual secondary outcomes (cardiac arrests, 1.64 vs 1.31, $p=0.736$; unplanned ICU admissions, 4.68 vs 4.19, $p=0.599$; and unexpected deaths, 1.18 vs 1.06, $p=0.752$). A reduction in the rate of cardiac arrests ($p=0.003$) and unexpected deaths ($p=0.01$) was seen from baseline to the study period for both groups combined.

Interpretation

The MET system greatly increases emergency team calling, but does not substantially affect the incidence of cardiac arrest, unplanned ICU admissions, or unexpected death.

3: Introduction: Patient Safety Research Team

- **Lead researcher - Professor Ken Hillman, MD**
 - Clinical Academic, Intensive Care Unit
 - University of New South Wales in Sydney, Australia
 - Field of expertise: intensive care medicine, health services research
- **Other team members**
 - Dr. Jack Chen
 - Dr. Rinaldo Bellomo
 - Dr. Simon Finfer
 - Dr. Arthas Flabouris



4: Background: Opening Points

- Cardiac arrest patients who die in general wards have often received delayed or inadequate care
 - Early intervention in response to physiological instability might prevent further deterioration in many patients
- Medical emergency team (MET) is a hospital-wide approach for early recognition of deterioration and early resuscitation
 - Developed in 1989
- MET system includes:
 - Staff education
 - MET calling criteria
 - Increased awareness of the dangers of physiological instability
 - Immediate availability of a MET

5: Background: Study Rationale

- Previous studies showed MET system associated with a reduction in unplanned ICU admissions, cardiac arrests and deaths
 - Despite the intuitive appeal of early intervention, MET system challenges traditional health care delivery by crossing many boundaries
- Research team hoped that further scientific proof could overcome some of these obstacles

6: Background: Setting Up a Research Team

- **Selecting collaborators**
 - Research team included statisticians, national professional bodies, high level managers and on-site project officers
 - Team members all attracted by the size and originality of the study
- **Funding**
 - Obtained by a peer-reviewed process through the National Health and Medical Research Council (NHMRC)

7: Methods: Study Design

- **Design: cluster randomized clinical trial**
 - Primary outcome was the composite of cardiac arrest, unexpected death, or planned ICU admission during a 6-month study period after MET activation
- **Objective:**
 - To investigate whether the medical emergency team (MET) system reduces the incidence of cardiac arrests, unplanned admissions to intensive care units (ICU), and deaths

8: Methods: Study Population and Setting

- **Setting:** of 46 hospitals assessed for eligibility, 23 randomized to control group (n=11) or to receive introduction of MET system (n=12)
 - Potential participating hospitals identified using the Australian Hospital and Health Services Yearbook
- **Eligibility criteria:**
 - Public hospitals with more than 20,000 estimated admissions/year
 - ICU and emergency department
 - No current MET system implemented

9: Methods: Outcome Measures

- **Primary outcome measure**
 - Composite of the incidence of cardiac arrests without a pre-existing not-for-resuscitation order, unplanned ICU admissions and unexpected deaths taking place in a general ward
- **Secondary outcome measure:**
 - Cardiac arrests without a pre-existing not-for-resuscitation order
 - Unplanned ICU admissions
 - Unexpected deaths

10: Methods: Data Collection

- Data collectors trained with standardized data collection manual
- Outcome and process measures obtained in all hospitals for a baseline period of two-months
 - Halfway through the baseline period, hospitals randomly assigned to control or intervention group
- Four-month educational strategy undertaken to prepare hospitals for the introduction of the MET system
 - In intervention hospitals (n=12), MET system was activated at the end of baseline period and made available for the next six-months
 - Practices in control hospitals (n=11) remained unchanged

11: Methods: Data Analysis and Interpretation

- **Calculated**
 - Sample size (Kerry and Bland method to account for clustering)
 - Cluster-level differences in event incidence (weighted t-test)
 - Individual level differences in event incidence (Rao-Scott chi-square test and adjusted t test)
 - Outcome-specific intraclass correlation coefficient and design factor
- **Multiple linear regressions to adjust for various factors**
- **Post-hoc exploratory analysis (paired weighted t test) to examine incidence difference between baseline and study period**

12: Results: Key Findings

- Overall rate of calls was significantly higher in MET hospitals than in control hospitals (3.1 vs. 8.7 per 1000 admissions)
 - Similar incidence of the composite primary outcome in the control and MET hospitals (5.86 vs 5.31 per 1000 admissions)
 - Both MET and control hospitals had similar incidence for individual secondary outcomes
 - Cardiac arrests: 1.64 vs 1.31
 - Unplanned ICU admissions: 4.68 vs 4.19
 - Unexpected deaths: 1.18 vs 1.06
- Incidence of cardiac arrests and unexpected deaths fell significantly from the baseline to the study period in all hospitals combined
- There was no significant difference in the change over time between the MET and control hospitals

13: Conclusion: Main Points

- **MET system increased emergency team calling, but does not affect the incidence of cardiac arrest, unplanned ICU admissions, or unexpected death**
- **Study findings suggest the need for:**
 - Improved intensive monitoring of patients in general wards
 - Rigorous documentation of patients' condition
 - Increased attention to education to ensure appropriate and timely response rates

14: Conclusion: Discussion

- **MET system did not significantly reduce the incidence of study outcomes. Possible explanations:**
 - MET is an ineffective intervention
 - MET is potentially effective but was inadequately implemented
 - Wrong outcomes were studied
 - Control hospitals contaminated as a result of being in the study
 - Hospitals studied were unrepresentative
 - Insufficient statistical power to detect important treatment effects
- **Limitations with previous studies have been the use of historical controls and the absence of randomization**

15: Conclusion: Study Impact

- **Academic**
 - One of the first major health services research projects to employ a rigorous scientific approach
 - Potential influence on funding organisations and researchers to conduct similar large scale scientific studies
- **Policy**
 - Many national, state/province and regional health authorities have mandated MET-type systems despite inconclusive results
- **Practice**
 - Despite inconclusive results, there has been widespread uptake of MET-type systems around the world
- **Patient**
 - Significant population benefits have been demonstrated in before/after studies, but not in the MERIT study

17: Conclusion: Practical Considerations

- **Study duration: 36 months**
 - 1 year preparation
 - 1 year study
 - 4 years analyzing data
- **Cost**
 - About \$1.0 million USD
- **Required resources:**
 - Wide range of researchers and clinicians with high level data entry and computing infrastructure
 - Support of the national Intensive Care Society to recruit the 23 hospitals
 - Goodwill and enthusiasm of participating hospitals



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18: Author Reflections: Lessons and Advice

- If the research team could change one thing in their research, they would include clearer upfront research questions for data analysis, for example:
 - Dose (MET calls)/response (outcomes) relationship
 - Relationship between baseline level of adverse events and improvement
 - Nature of interventions performed at time of MET

19: Author Reflections: Lessons and Advice (2)

- **Advice for researchers:**
 - *"The greatest opportunities for improvement in health care and patient safety are at the interfaces of care, between the traditional silos."*
 - Multidisciplinary research (e.g. statisticians, clinicians, qualitative researchers) is critical for original patient safety research
- **Initial barriers were largely logistical**
 - Getting 23 hospitals involved
 - Identifying reliable champions in each hospital
 - Communicating well

20: Author Reflections: Lessons and Advice (3)

- MET concept is simple and easily applicable to the most basic hospitals. However, evaluation and research is more difficult
- Complexity, expense and relevance may make this research largely unfeasible for developing countries in its current form
 - Would require significant adaptations based on local particularities
 - However, could implement simple version of MET system with simplified local evaluation
 - E.g.: staff feedback potentially preventable precursors to hospital deaths and cardiac arrests

21: Author Reflections: Selecting Design

- Randomisation judged to be the most rigorous methodology available but had to be based on clusters (individual institutions) not patients. Factors in this choice also included:
 - Costs
 - Infrastructure to conduct the study
 - Co-operation of many hospitals
 - Research expertise
 - Level of scientific rigour
- Other potential methodologies included:
 - Attempting to define, in a prospective fashion, potentially preventable antecedents to hospital deaths and serious adverse events
 - Before/after studies in one institution
 - Case control studies in several institutions

22: Author Reflections: Ideas for Future Research

- Investigation of serious illness where further active treatment would be futile
 - I.e. establish systems for “dying safely” and “living safely”
- Evaluation of a parallel system to the MET: one for early recognition and care of dying patients
 - Hospitalised patients are becoming older with many co-morbidities and are often admitted even when care is futile
 - MET system can become the surrogate “dying” team for a hospital

23: Additional References

- Cretikos M, Chen J, Hillman K, Bellomo R, Finfer S, Flabouris A, the MERIT Investigators. The objective medical emergency team activation criteria: A case-control study. *Resuscitation* 2007;73:62-72.
- Creitkos M, Chen J, Hillman K, Bellomo R, Finfer S, Flabouris A, the MERIT Study Investigators. The effectiveness of MET system implementation and factors associated with the level of MET utilisation during the MERIT study. *Crit Care Resus* 2007;9:206-212.
- Cretikos M, Bellomo R, Hillman K, Chen J, Finfer S, Flabouris A. Respiratory rate: the neglected vital sign. *Med J Aust* 2008;188:657-659.
- Chen J, Bellomo R, Flabouris A, Hillman K, Finfer S, the MERIT Study Investigators. The relationship between early emergency team calls and serious adverse events. *Crit Care Med* (in press).
- MERIT Study Investigators. The medical emergency team system and not-for-resuscitation orders: Results from the MERIT study. *Resuscitation* (in press).

24: Additional References (2)

- Chen J, Hillman K, Bellomo R, Flabouris A, Finfer S, the MERIT Study Investigators. The impact of introducing medical emergency teams on the documentation of vital signs. Resuscitation (in press).
- Flabouris A, Chen J, Hillman K, Bellomo R, Finfer S, the MERIT Study Investigators. Timing and intervention of emergency teams during the MERIT study. Intensive Care Med (submitted).
- The MERIT Study Investigators. The reasons for calling an emergency team between control and MET hospitals (in preparation).
- Chen J, Flabouris A, Bellomo R, Hillman K, Finfer S, the MERIT Study Investigators. The relationship between baseline incidence of serious adverse events and its change following the introduction of a medical emergency team (in preparation).